U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

d14646
HFI-35
(Purged Copy)

Telephone: [718] 340-7000 [EXT 5301]

WARNING LETTER

FEB 23 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dite Van Clief
President
Euro-American Brands, LLC
15 Prospect Street
Paramus, NJ 07652

Ref: 19-NYK-98

Dear Mr. Van Clief:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On January 5 and 7, 1998 FDA examined various packaged chocolate confectionery products at Ultimate Distribution, 50 Executive Avenue, Edison, NJ. These products were offered for admission into the United States through the Port of New York/New Jersey under entry number W82-0014126-6, dated November 12,1997. Our examination of 6 items from this shipment consisting of [redacted] cases found only 76 cases remained as follows:

ENTRY LINE#	PRODUCT	ORIGINAL QTY.	REMAINING QTY.
2-6	White choc/nuts/rice	[redacted] cases	5 cases
2-7	Milk choc/honey/yogurt/nut	[redacted] cases	1 case
2-8	Milk choc/praline	[redacted] cases	4 cases
2-9	Milk choc/yogurt	[redacted] cases	1 case
2-10	Plain choc/peppermint	[redacted] cases	4 cases
2-11	Assorted mini chocolate bars	[redacted] cases	61 cases

Mr. Dite Van Chief, President
Euro-America Brands, LLC

The product location of these items was provide to FDA on December 30, 1997 by your import broker, J.H. Bachman, Jersey City, NJ. The above 6 items were shipped throughout the month of December 1997, as evidenced by the Ultimate Distribution's records (copy attached) without receiving clearance from the FDA.

This action taken by your firm is in violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release which merely permits you to take possession of the shipment. When other Federal agencies, such as FDA also exercise jurisdiction over a product offered for importation, their release must also be obtained before a product may be legally distributed.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice, such as seizure, injunction, or automatic detention to ensure that imported products are held intact until released by FDA. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the reoccurrence of the violation.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal or commercial information purged.

Mr. Dite Van Chief, President
Euro-American Brands, LLC

Your response should be addressed to the Food and Drug Administration, Attention: Joseph V. Sollazzo - Compliance Officer, Port Elizabeth Resident Post, 1201 Corbin Street, Port Elizabeth, New Jersey 07201 (telephone 1-732-645-2386 extension 20).

Sincerely,

Brenda Holman
District Director
New York District Office

Enclosure: December 1997 Distribution Records